**IN THE UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF TENNESSEE**

**WESTERN DIVISION**

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| WESLEY FOWLER;<br><br>Plaintiff,<br><br>vs.<br><br>AUXILIUM PHARMACEUTICALS, INC.; GLAXOSMITHKLINE, LLC; and DOES 1-50 INCLUSIVE,<br><br>Defendants. | Case No.<br><br>**COMPLAINT FOR:**<br><br>1) STRICT LIABILITY: DESIGN DEFECT<br>2) NEGLIGENCE<br>3) FAILURE TO WARN<br>4) BREACH OF EXPRESS WARRANTY<br>5) BREACH OF IMPLIED WARRANTY<br>6) FRAUD: MISREPRESENTATION<br>7) FRAUD: CONCEALMENT<br>8) FRAUD: NEGLIGENT MISREPRESENTATION<br>9) VIOLATION OF UNFAIR AND DECEPTIVE TRADE PRACTICE LAWS<br><br>**DEMAND FOR JURY TRIAL** |

Plaintiff Wesley Fowler, by and through the undersigned counsel, hereby files this Complaint for Damages and Jury Demand against Defendants Auxilium Pharmaceuticals, Inc.; GlaxoSmithKline, LLC; and DOES 1 through 50, and each of them, inclusive (hereinafter jointly "Defendants") and in support, states as follows:

## I. INTRODUCTION

1. Defendants created a disease called "low T," characterized by aging, stress, depression, and lethargy, which were to be treated with prescription testosterone in the form of gels, patches, pellets, and injections.

2. Defendants misrepresented that prescription testosterone is a safe and effective treatment for hypogonadism, "low testosterone," or "low T," when prescription testosterone can cause

serious injuries, including heart attack, stroke, thrombotic events, and other serious health conditions.

3. As a result of Defendants conduct, diagnoses of hypogonadism through "Low T" and prescriptions for testosterone replacement therapy have increased substantially. For example, Sales of Testim were $233.4 million in 2012.

4. Plaintiff was diagnosed with "low testosterone" and was prescribed testosterone. As a result of his prescription testosterone use, Plaintiffs suffered serious and permanent injuries, and thus seeks damages relating to the Defendants' development, design, testing, labeling, packaging, manufacturing, selling, marketing, advertising, promotion, and distribution of prescription testosterone.

## II. PARTIES

5. At all times relevant to this action, Plaintiff Wesley Fowler has been a resident and citizen of Tennessee.

6. Defendant Auxilium Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with headquarters and principle place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087. At all times relevant herein, Defendant Auxilium Pharmaceuticals was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Testim in the State of Tennessee.

7. Defendant, GlaxoSmithKline, LLC ("GSK"), is a wholly owned subsidiary of GlaxoSmithKline, a British public limited company. GSK maintains headquarters and a principle place of business at the Philadelphia Navy Yard, 5 Crescent Drive, Philadelphia, Pennsylvania 191122. At all times relevant herein, GSK was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Testim in the State of Tennessee.

8. Plaintiff does not know the true names and capacities of DOES 1-50 inclusive. Plaintiff will seek leave to amend when the true names and identities of said fictitiously named defendants are ascertained. At all relevant times herein, DOES 1-50 inclusive were the

individuals, corporations, and/or business entities, which were agents, servants, joint ventures, partners, co-conspirators, participants or otherwise ratified the conduct of the other Defendants as alleged herein.

9. At all relevant times, Defendants acted in concert with one another to fraudulently convey false and misleading information concerning the safety and efficacy of prescription testosterone and to conceal the risks of serious adverse events, including heart attack, stroke, and other adverse effects associated with prescription testosterone from the public, Plaintiff, physicians, and other healthcare providers. These concerted efforts resulted in significant harm to those treated with prescription testosterone including Plaintiff. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiff would not have used prescription testosterone.

10. The combined acts and/or omissions of each Defendant resulted in indivisible injury to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

## III. VENUE & JURISDICTION

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because there is complete diversity of citizenship between Plaintiff and Defendants and the amount in controversy exceeds $75,000, exclusive of interest and costs.

12. This Court has personal jurisdiction over Defendants. Defendants are and were at all relevant times authorized to conduct business in Tennessee and Defendants conducted such business within the state including the performance of acts that caused or contributed to the harm giving rise to this action.

13. At all relevant times, Defendants maintained systematic and continuous contacts in this judicial district, regularly transacted business within this judicial district, employed numerous individuals in this district and regularly availed themselves of the benefits of this judicial district.

Defendants received substantial financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling and distributing prescription testosterone in this district and throughout the United States.

14. Venue properly lies in this district pursuant to 28 U.S.C. § 1391(a) because a substantial number of the events, actions, or omissions giving rise to Plaintiff's claims occurred in this district. At all relevant times, Defendants conducted substantial business in this district. In addition, Defendants are subject to personal jurisdiction in this district.

## IV. GENERAL ALLEGATIONS

### A. BACKGROUND

15. Testosterone is an androgen and a hormone. In males, testosterone is responsible for many normal functions, including growth and development of the genitals, muscles, and bones. It also helps cause normal sexual development (puberty) in boys. It works by affecting many body systems so that the body can develop and function normally. In men, testosterone levels normally begin a gradual decline after the age of thirty.

16. Testosterone replacement therapy is prescribed for hypogonadism, which is diminished activity of the testes in men. One of the symptoms is low testosterone. The FDA has approved testosterone therapy only for men who lack or have low testosterone associated with medical conditions, such as when the testicles fail to produce testosterone. Testosterone therapy as an FDA-approved treatment for hypogonadism has been used in some adolescent boys to cause puberty in those with delayed puberty.

17. Prescription testosterone injections have been approved for over 60 years; however, with the rise in marketing of testosterone treatment, a number of products are now widely available.

18. Testosterone stimulates red blood cell production and an increase in red blood cells is called polycythemia. Polycythemia can be accompanied with an increase in hemoglobin and hematocrit, which can lead to increased blood viscosity. Therefore, administering exogenous

(outside the body) testosterone can lead to polycythemia, which increases stroke and heart attack risk.

19. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood; however, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Therefore, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

## B. PRESCRIPTION TESTOSTERONE PRODUCTS

20. Prescription testosterone comes in the form of gels, patches, pellets, tablets, and injections.

21. Testim 1% is a testosterone-containing topical gel. Testim provides a continuous transdermal delivery system for testosterone for 24 hours following a single application to the skin of the shoulders and/or upper arms in men.

22. Testim was originally developed by Bentley Pharmaceuticals, Inc., and was exclusively licensed to Auxilium for manufacture and sale worldwide. The license was and continues to be royalty-bearing.

23. The FDA approved Testim on October 31, 2002. In early 2003, Auxilium launched Testim in the United States as a form of testosterone replacement therapy. Auxilium uses its sales force to market Testim in the United States, which includes physician-detailing and direct-to-consumer marketing through a variety of advertising platforms, including the Internet.

24. On or about May 21, 2012, Auxilium and GSK entered into an agreement for the co-promotion of Testim. Under the terms of the agreement, Auxilium granted GSK the exclusive right to co-promote the sale of Testim with Auxilium in the United States through September 30, 2015. *See* http://us.gsk.com/html/media-news/pressreleases/2012/2012-pressrelease-1097601.htm.

25. Upon information and belief, GSK has promoted Testim using a sizeable established field sales force which has relationships with current prescription testosterone prescribers, including

primary care physicians, in the United States. These GSK sales representatives currently promote a range of products, including Testim. *See id.*

### C. PRESCRIPTION TESTOSTERONE EFFECTS AND INJURIES

26. According to the Food and Drug Administration:

> Testosterone products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone, because of reasons such as genetic problems or chemotherapy. Other examples include problems with brain structures, called the hypothalamus and pituitary that control the production of testosterone by the testicles.

FDA Safety Announcement, "FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products," January 31, 2014.

27. According to an Institute of Medicine report published in 2004, "A systematic review of the medical literature on testosterone therapy, particularly placebo-controlled trials in older men, demonstrated that there is not clear evidence of benefit for any of the health outcomes examined," which included bone health, body composition and strength, physical function, cognitive function, mood and depression, sexual function, and health-related quality of life.

28. Prescription testosterone may produce undesirable side effects to patients who use the drug, including but not limited to death, cardiovascular events, stroke, and thrombotic events.

29. Due to the increased production of red blood cells from testosterone therapy, hemoglobin and hematocrit levels increase after testosterone administration and may take as long as 90 days to return to baseline levels.

30. There have been studies suggesting that testosterone in men increases the risk of cardiovascular events, such as heart attacks and strokes.

31. In 2010, a *New England Journal of Medicine Study* entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events. Out of 106 men taking testosterone in the study, 23 experienced cardiovascular-related events (including heart attacks and atrial fibrillation) compared to 5 in the 103-man control group who had not used the prescription testosterone gel.

32. In November of 2013, a study was published in the *Journal of the American Medical Association* entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" which indicated that testosterone therapy raised the risk of death, heart attack, and stroke by about 30%.

33. On January 29, 2014, a study was released in *PLoS ONE* entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a previous diagnosis of heart disease.

34. Thrombotic events, such as pulmonary embolism, deep vein thrombosis, and other serious blood clots have been identified as adverse events reported by prescription testosterone users, although they have not been highlighted in the labels.

35. Additional side effects of prescription testosterone include: acne; skin irritation (where testosterone is applied); increased cholesterol levels; increased prostate specific antigen; increased red blood cell count requiring patients to frequently donate blood; increased liver function tests; and excessive frequency and duration of erections.

36. Secondary exposure to prescription can cause side effects in others. In 2009, the FDA issued a black box warning for AndroGel prescriptions, advising patients of reported virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with prescription testosterone.

## D. TESTOSTERONE MARKETING AND PROMOTION

37. Defendants' marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

38. Defendants coordinated an advertising campaign designed to convince men that they suffered from low testosterone. Defendants orchestrated a national disease awareness campaign that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential prescription testosterone users, and online media including the unbranded website "IsItLowT.com."

39. Television advertisements for testosterone suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experiences any of the "symptoms" of low testosterone. These "symptoms" include listlessness, creased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

40. Defendants' national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone including "Have you experienced a recent deterioration in your ability to play sports?", "Are you falling asleep after dinner?", "Are you sad and/or grumpy?", and "Do you have a lack of energy?"

41. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morely drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morely admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used

on the "IsItLowT" website. Natasha Singer, Selling that New-Man Feeling, Nov. 23, 2013, N.Y. TIMES.

42. Since the FDA approved Testim, Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

43. While running its disease awareness campaign, Defendants promote their product Testim as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

44. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

45. Defendants successfully created a robust and previously nonexistent market for their drug and also benefitted from the media campaign of fellow testosterone replacement therapy manufacturer Abbott Laboratories spent $80 million promoting its AndroGel prescription testosterone in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

46. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, Are Testosterone Drugs the Next Viagra?, May 10, 2012, Bloomberg BusinessWeek, available at: http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

47. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance low T. See Singer, Selling That New-Man Feeling, supra; See also, Larry Dobrow, All-star large pharma marketing team of the year: Androgel. Jan. 2, 2013, Medical Marketing & Media, available at: http://www.mmm-online.com/all-star-large-pharmamarketing- team-of-the-year-androgel/article/273242/.

48. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of prescription testosterone is safe for human use, even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

49. Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed and that conditions associated with normal aging could be caused by low testosterone levels.

## E. FALSE AND MISLEADING MARKETING AND PROMOTIONS

50. Defendants successfully marketed prescription testosterone by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

51. Marketing practices included ghostwriting by professional medical writers to craft messages for physicians and consumers of "low T" products. Articles in the Journal of the American Medical Association's *Internal Medicine* described how a prescription testosterone maker paid "for the creation of apparently objective physician or consumer education media products," including cutting the following cautionary sentences from a monograph Stephen R. Braun had written regarding testosterone replacement therapy:

> It is worth noting that the quality of the evidence on which current clinical guidelines for TRT are based is low or very low, and that similar guidelines about

> the alleged benefits of hormone therapy for post-menopausal women have been questioned after high-quality studies of sufficient size and duration were carried out.[]
>
> Composite measures of T levels and the symptoms related to low circulating androgens are likely to be fluid and lack stability over long periods of time. This suggests that Symptomatic Androgen Deficiency (SAD) represents a transient, rather than a permanent, state for the majority of the general male population and may cast doubt on the use of SAD or similar constructs as proxies for true age-related hypogonadism.[]

Stephen R. Braun, "Promoting 'Low T': A Medical Writer's Perspective, *JAMA Internal Medicine*, 173(15), August 12/26, 2013.

52. Defendants' advertising program, sought to create the image and belief by consumers and their physicians that the use of prescription testosterone was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

53. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using prescription testosterone. Defendants deceived potential prescription testosterone users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

54. Defendants concealed material relevant information from potential prescription testosterone users and minimized user and prescriber concern regarding the safety of prescription testosterone.

55. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represents that Defendants adequately tested prescription testosterone for all likely side effects.

56. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Testim. If Plaintiff in

this action had known the risks and dangers associated with Testim, Plaintiff would not have taken Testim and consequently would not have been subject to its serious side effects.

## F. PLAINTIFF-SPECIFIC ALLEGATIONS

57. Plaintiff was 46 years old when he first was prescribed Testim and he used as directed from March 2011 until November 2013.

58. Plaintiff used prescription testosterone to treat symptoms he and his health care providers attributed to low testosterone as a result of Defendants' advertisements and promotion.

59. On September 11, 2013, Plaintiff's doctors discovered that Plaintiff had stenosis in multiple arteries. As a result of this injury, Plaintiff was required to undergo angiographies on September 18, 2013; October 25, 2013; and November 25, 2013. Plaintiff's doctors placed multiple stents in his arteries following his diagnosis.

60. Plaintiff used Testim manufactured, marketed, sold, promoted, and/or distributed by Defendants. The prescription testosterone reached Plaintiff without substantial change in the drug's condition.

61. At all relevant times, Defendants had knowledge that there was a significant increased risk of adverse events associated with Testim and despite this knowledge Defendants continued to manufacture, market, distribute, sell, and profit from sales of Testim.

62. Despite such knowledge, Defendants knowingly, purposely and deliberately failed to adequately warn Plaintiff, patients, consumers, medical providers and the public of the increased risk of serious injury associated with using Testim, including but not limited to death, cardiovascular events, stroke, and thrombotic events.

63. Plaintiff's prescribing physician may not have prescribed Testim to Plaintiff had Defendants provided said physician with an appropriate and adequate warning regarding the risks associated with the use of Testim.

64. Plaintiff's prescribing physician may have changed the way in which the physician treated Plaintiff's relevant condition, warned Plaintiff about the signs and symptoms of serious

adverse effects of Testim, and discussed the true risks of heart attack, stroke, and other serious adverse events, had Defendants provided said physician with an appropriate and adequate warning regarding the risks associated with the use of Testim.

65. As a direct and proximate result of Defendants' negligence, omissions, misrepresentations, failure to warn, willful and intentional acts, and other culpable conduct, Plaintiff suffered significant injuries from the use of Testim, including severe and permanent bodily injury, pain and suffering, disability, mental anguish and loss of capacity for the enjoyment of life, and the expense of medical and nursing care.

66. Had Plaintiff known the true risks associated with the use of prescription testosterone, including Testim, he would not have incurred the injuries or damages he did as a result of his use of Testim.

67. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

## V. DELAYED DISCOVERY

68. Defendants, through their affirmative misrepresentations and omissions, actively concealed from the Plaintiff and Plaintiff's physicians and healthcare providers the true and significant risks associated with prescription testosterone, including Testim.

69. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians and healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

70. Plaintiff first learned of the risks associated with Testim and Defendants' concealment of those risks in 2014, when Plaintiff first saw television advertisement about litigation involving the use of prescription testosterone in men.

71. No limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between the use of Testim and the harm suffered as a result. As such, Plaintiff hereby invokes the discovery rule based on the fact that this Complaint is filed well within the statutory period after Plaintiff knew or should have known the facts alleged herein.

72. Additionally, the accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

73. Additionally, each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

## VI. CAUSES OF ACTION

### G. FIRST CAUSE OF ACTION

### STRICT LIABILITY: DESIGN DEFECT

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

74. At all relevant and material times, the Defendants designed, manufactured, packaged, marketed, advertised, promoted, distributed, and sold prescription testosterone placing the products into the stream of commerce.

75. At all relevant and material times, prescription testosterone was designed, manufactured, packaged, marketed, advertised, promoted, distributed, and sold by Defendants in a defective and unreasonably dangerous condition.

76. Prescription testosterone was expected to reach, and did reach, users and consumers, including Plaintiff, without substantial change in their defective and unreasonably dangerous condition.

77. Prescription testosterone was used by Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

78. Prescription testosterone was defective and unreasonably dangerous when each product entered the stream of commerce in one or more of the following ways:

a. They contained defects in that the each product caused and/or increased the risk of experiencing an adverse event, including but not limited to heart attack, stroke, and death.

b. They were not safe because the health risks associated with each product outweighed the benefits.

c. They were marketed and promoted for use when they carried an unreasonable and unnecessary risk of serious injury.

d. They were insufficiently and/or inadequately tested by Defendants.

e. They were not safe due, in part, to inadequate and defective instructions and inadequate and defective warnings provided by Defendants.

f. They were unreasonably dangerous in that, as designed, the risks of serious injury posed by using the products exceeded any benefits the products were designed to or might in fact bestow.

g. They were defective in design in that the products neither bore, nor were packaged with, nor were accompanied by, warnings adequate to alert users, including Plaintiff, of the increased risks associated with using the products, including, but not limited to, the risk of serious injury.

h. They were not accompanied by adequate warnings and instructions for use that included adequate information to fully apprise users, consumers, and the medical, pharmaceutical and scientific communities of the potential risks and serious side effects associated with using the products.

i. They were unsafe for normal or reasonably anticipated use. Said products were defective and unreasonably dangerous in design, construction and/or composition.

j. They were defective and unreasonably dangerous because the products did not conform to an express warranty of the manufacturer about the product.

k. They were defective and unreasonably dangerous due to inadequate warnings, inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

79. Prescription testosterone as manufactured and supplied by the Defendants were defective due to inadequate warnings and instructions because, after Defendants knew or should have known of the risk of injuries from use, Defendants failed to provide adequate warnings to the medical community and the consumers to whom the drugs were directly marketed and advertised; and, further, Defendants continued to affirmatively promote prescription testosterone as safe and effective.

80. A reasonable person who had actual knowledge of the increased risks associated with using prescription testosterone would have concluded that prescription testosterone should not have been marketed to or used.

81. Despite the fact that Defendants knew or should have known of the defective nature of Testim, Defendants continued to design, manufacture and sell Testim so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by Testim.

82. Plaintiff and the non-defendant health care providers involved could not, through the exercise of reasonable care, have discovered the risk of serious injury associated with and/or caused by Testim.

83. Plaintiff was not aware of the aforementioned defects at any time prior to the injuries caused by Testim.

84. Had adequate information regarding the safety of the products been provided to Plaintiff, Plaintiff would not have used Testim.

85. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

86. As a direct and proximate consequence of Defendants negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory, exemplary and punitive damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## H. SECOND CAUSE OF ACTION – NEGLIGENCE

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

87. Defendants negligently manufactured, designed, labeled, packaged, distributed, marketed, advertised, promoted, and sold Testim.

88. At all relevant and material times, Defendants had a duty to Plaintiff to exercise reasonable care in the design, manufacture, advertising, marketing, labeling, packaging, distribution, post-market safety monitoring, reporting of adverse events, and sale of Testim, including a duty to ensure that the products did not cause users such as Plaintiff to suffer from unreasonable, dangerous side effects when used alone or in foreseeable combination with other drugs.

89. Defendants breached their duty of care to Plaintiff and were negligent in their actions, misrepresentations, and omissions in numerous ways including the following:

a. Failing to perform adequate testing concerning the safety of Testim which would have shown Testim posed a serious risk of death, cardiovascular events, stroke, thrombotic events, and other adverse effects which would have permitted adequate and appropriate warnings to have been by given by Defendants to prescribing physicians and the consuming public, including Plaintiff;

b. Failing to design Testim so as to properly minimize effects on receptors that were known to be associated with certain serious adverse effects;

c. Failing to develop Testim properly so as to minimize the proliferation of new uses for which there was little or no scientific evidence of safety and efficacy;

d. Failing to conduct adequate pre-clinical and clinical testing to determine the safety of Testim, including failing to adequately train clinical investigators as to the risks and benefits of Testim and as to proper methods of monitoring patients;

e. Failing to report to the FDA, the medical community, and the general

f. public those data resulting from pre- and post-marketing tests of Testim which indicated risks associated with using the products;

g. Failing to conduct adequate post-market monitoring and surveillance of Testim and analysis of adverse event reports;

h. Designing, manufacturing, marketing, advertising, distributing, and selling Testim to consumers, including Plaintiff, without an adequate warning of risks associated with using the products and without proper and adequate instructions to avoid the harm which could foreseeably occur as a result of using the products;

i. Failing to exercise due care when advertising, promoting, and selling Testim;

j. Failing to use due care in the preparation, design and development of Testim to prevent, avoid, or minimize the risk of injury to individuals when the products were used;

k. Failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;

l. Failing to accompany Testim with proper warnings regarding all possible risks associated with using the products;

m. Failing to use due care in the manufacture, inspection, and labeling of Testim to prevent risk of injuries to individuals who used the products;

n. Failing to provide adequate and accurate training and information to the sales representatives who sold the products;

o. Failing to conduct sales of Testim properly in that Defendants' sales representatives made false and misleading statements to prescribers concerning approved and unapproved uses, risks and benefits of Testim;

p. Failing to educate healthcare providers and the public about the safest use of the products;

q. Failing to give healthcare providers adequate information to weigh the risks of serious injury associated with the products;

r. Failing to test and inspect Testim in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, and sold;

s. Failing to warn Plaintiff of the danger of adverse medical conditions from the use of Testim;

t. Failing to label Testim to adequately warn Plaintiff of the serious adverse side effects with the use of Testim; and

u. Failing to refrain from illegal off-label marketing.

90. Defendants advertised, promoted, marketed, sold and distributed Testim despite the fact that Defendants knew or should have known of the increased risks associated with using the products, including but not limited to death, cardiovascular events, stroke, thrombotic events, and other adverse events of which Plaintiff and his healthcare providers would not have been aware.

91. Defendants, individually and collectively, had a duty to warn the FDA, their customers, the medical community and the public about the increased risks of injury but failed to do so.

92. Defendants are guilty of negligence per se in that the Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq., and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations.

a. The Defendants' acts and omissions, including but not limited to Defendants' off-label marketing, constitute an adulteration and/or misbranding as defined by the

Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* Persons such as Plaintiff were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of Plaintiff's injury.

b. The Defendants' also failed to report adverse events as required by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* Persons such as Plaintiff were the parties intended to be protected by such legislation and whose injuries said regulations were designed to prevent. Defendants' conduct was a proximate cause of Plaintiff's injury.

93. Despite the fact that Defendant knew or should have known that Testim increased the risk of serious injury including but not limited to heart attack, stroke,, and other adverse effects, Defendant continued to manufacture, market, advertise, sell and distribute Testim to consumers, including Plaintiff.

94. Defendants negligently and recklessly represented to Plaintiff, physicians, and other persons and professionals Defendants knew would justifiably rely on the representations, that Testim was safe to use and that the utility of the products outweighed any risk in use for their intended purposes.

95. Defendants negligently and recklessly failed to disclose to Plaintiff and others important safety and efficacy information about Testim, thereby suppressing material facts while under a duty to disclose such information.

96. Defendants' representations about the safety and adverse side effects of Testim was negligently and recklessly made in that Testim in fact caused injury, was unsafe, and the benefits of its use far outweighed by the risk associated with use thereof.

97. Defendants knew or should have known that their representations and omissions were false. Defendants made such false, negligent and reckless representations and omissions with the intent or purpose that Plaintiff and any non-defendant physicians would rely upon such representations, leading to the use of Testim as described.

98. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Testim including serious injury. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Testim.

99. At the time Defendants made these misrepresentations and/or omissions, they knew or should have known that Testim was unreasonably dangerous and not what Defendants had represented to Plaintiff, as well as the medical community, the FDA and the consuming public.

100. Defendants' misrepresentations and/or omissions were undertaken with an intent that doctors and patients, including Plaintiff, rely upon them.

101. Plaintiff and his healthcare providers did not know that these representations were false and justifiably relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of Testim to employ these products.

102. Had Plaintiff been aware of the increased risk of side effects associated with Testim and the relative efficacy of Testim compared with other readily available products, Plaintiff would not have used these products.

103. As a direct and proximate consequence of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seek compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## I. THIRD CAUSE OF ACTION

## STRICT LIABILITY: FAILURE TO WARN

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action, and further alleges:

104. Testim is unreasonably dangerous, even when used in a foreseeable manner as designed and intended by Defendants.

105. Defendants failed to warn and/or adequately warn Plaintiff, consumers, physicians, and healthcare professionals of the increased health risks associated with using Testim.

106. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to him.

107. Defendants had a continuing duty to warn consumers and healthcare professionals of increased health risks associated with its products, and negligently and/or wantonly breached its duty as follows:

a. Failed to include warnings and/or adequate warnings of the increased risks of serious injury associated with using Testim including but not limited to adverse cardiovascular effects;
b. Failed to provide adequate and proper instructions regarding the proper use of Testim to prevent heart attack, stroke, and other adverse effects;
c. Failed to provide adequate and/or proper instructions regarding the need for diagnostic tests to be performed on the patient prior to and during use of Testim to discover and ensure against serious and potentially fatal side effects including but not limited to heart attack, stroke, and other adverse effects;
d. Failed to inform Plaintiff that Testim had not been adequately tested to determine the safety and risks associated with using the products;
e. Failed to warn that the risks associated with the use of Testim exceeded the risks of other available forms of treatment for Plaintiff's condition, including the risks of heart attack, stroke, and other adverse effects; and
f. Failed to report adverse events to the FDA associated with the application and/or injection of Testim.

108. Defendants and each of them had a duty to warn the FDA, the medical community, Plaintiff, and Plaintiff's physicians about the increased risks of injury but failed to do so.

109. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## J. FOURTH CAUSE OF ACTION

## BREACH OF EXPRESS WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

110. Defendants expressly represented to Plaintiff, consumers and the medical community that Testim was:

a. safe;
b. efficacious;
c. of merchantable quality;
d. adequately tested;
e. well tolerated in adequate and well-controlled clinical studies; and
f. did not increase the risk of experiencing serious, life threatening side effects.

111. Defendants breached the express warranties as follows:

a. Defendants misrepresented the safety of Testim in the products' labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions;
b. Defendants misrepresented the risks associated with using Testim;

c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury;

d. Defendants misrepresented that Testim was as safe or safer than other available forms of treatment for Plaintiff's condition; and

e. Defendants fraudulently concealed information about the safety of Testim, including information that the products were not safer than other available forms of treatment for Plaintiff's condition.

112. Testim did not conform to Defendants' express representations and warranties.

113. At all relevant times, Testim did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

114. At all relevant times, Testim did not perform in accordance with the Defendants' representations because Testim is not safe and cause high levels of serious side effects.

115. In deciding to purchase and use Testim, Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

116. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## K. FIFTH CAUSE OF ACTION

## BREACH OF IMPLIED WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

117. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold Testim.

118. Defendants impliedly warranted to Plaintiff that Testim was safe for use by Plaintiff and the consuming population.

119. Defendants knew of the use for which Testim was intended and impliedly warranted Testim to be of merchantable quality and safe and fit for their intended use.

120. Plaintiff and his healthcare providers used Testim as intended and directed by the Defendants and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

121. Plaintiff was a foreseeable user of Defendants' product, Testim. Testim was expected to reach and did in fact reach Plaintiff, without substantial change in the condition in which the products were manufactured and sold by Defendants.

122. Plaintiff and his healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon the Defendants' implied warranty that Testim was safe, of merchantable quality, and fit for use.

123. The Testim used by Plaintiff was not safe, of merchantable quality, nor fit for use.

124. The Testim used by Plaintiff did not perform in accordance with Defendants' representations because Testim is not safe and causes high levels of serious, life-threatening side effects.

125. Defendants breached the implied warranty in that Testim did not conform to Defendants' representations.

126. As a direct and proximate result of the breach of warranty of merchantability and the warranty of fitness by Defendants, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## L. SIXTH CAUSE OF ACTION

## FRAUD: MISREPRESENATION

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

127. At all relevant and material times, Defendants falsely and fraudulently represented to Plaintiff's physicians, and through them, to Plaintiff and members of the general public, that Testim products were safe to treat low testosterone, that they had few side effects, and would not interfere with their daily lives.

128. Defendants' superior knowledge and expertise, relationship of trust and confidence with doctors and the public, specific knowledge regarding the risks and dangers of Testim, and intentional dissemination of promotional and marketing information about Testim for the purpose of maximizing sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the products.

129. At all times herein mentioned, Defendants fraudulently represented to Plaintiff, physicians, and other persons and professionals whom Defendants knew would justifiably rely on Defendants' representations, as well as the public at large, that Testim was safe and effective for use in treating Plaintiff's conditions.

130. Defendants intentionally failed to disclose to Plaintiff and others important safety, risk, adverse event and injury information, including but not limited to the increased risk of heart attack, stroke, and other adverse effects. Defendants suppressed material facts about the products while having a duty to disclose such information, which duty arose, in part, from the Defendants designing, manufacturing, marketing, advertising, distributing and selling such products.

131. Defendants' false representations were fraudulently made, with the intent or purpose that Plaintiff and healthcare providers involved in providing treatment to Plaintiff would justifiably rely upon them, leading to the use of Testim.

132. Defendants' deliberate misrepresentations and/or concealment, suppression, and omission of material facts as alleged herein, include, but are not limited to:

a. Making false and misleading claims regarding the known risks of Testim and suppressing, failing to disclose and mischaracterizing the known risks of Testim, including, but not limited to, stroke, heart attack, and death;

b. Misrepresenting or failing to timely and fully disclose the true results of clinical tests and studies related to Testim;

c. Issuing false and misleading warnings and/or failing to issue adequate warnings concerning the risks and dangers of using Testim which would disclose the nature and extent of the harmful side effects of Testim;

d. Making false and misleading claims that adequate clinical testing had been done and/or failing to disclose that adequate and/or generally accepted standards for pre-clinical and clinical testing had not been followed; and

e. Making false and misleading misrepresentations concerning the safety, efficacy and benefits of Testim without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

133. Defendants willfully, wantonly, and recklessly disregarded their duty to provide truthful representations regarding the safety and risk of Testim.

134. Defendants made these misrepresentations with the intent that doctors and patients, including Plaintiff, rely upon them.

135. Defendants' misrepresentations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Testim.

136. Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

137. Defendants omitted, misrepresented, suppressed and concealed material facts concerning the dangers and risk of injuries associated with the use of Testim including the increased risk of serious injury as well as the fact that the product was unreasonably dangerous.

138. Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Testim in order to increase sales.

139. Plaintiff and the treating medical community did not know that Defendants' representations were false and/or misleading and justifiably relied on them.

140. Defendants had sole access to material facts concerning the dangers and unreasonable risks of Testim.

141. The intentional concealment of information by Defendants about the substantial risks of serious injury associated with Testim was known by Defendants to be wrongful.

142. Had Defendants not fraudulently concealed such information, Plaintiff would not have used Testim.

143. Had Plaintiff been aware of the increased risks of serious injury associated with Testim, Plaintiff would not have used Testim.

144. As a direct and proximate consequence of Defendants' fraudulent and intentional misrepresentation, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees and such other, and further relief as this Court deems just and proper.

## M. SEVENTH CAUSE OF ACTION

## FRAUD: CONCEALMENT

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

145. At all relevant and material times, Defendants had the duty and obligation to disclose to Plaintiff's physicians, and through them, to Plaintiff and members of the general public, the fact that Testim is dangerous and defective as well as the likelihood of serious consequences to Plaintiff and other users and the level of risk involved in prescribing testosterone for the purpose indicated. Defendants made affirmative representations set forth above to Plaintiff and Plaintiff's health care providers and the general public prior to the day Plaintiff was first prescribed and used Testim while concealing material facts.

146. Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's health care providers the facts concerning Testim, including that the use of and exposure to Testim could cause severe injuries, including but not limited to life-threatening cardiac events, strokes, and thrombotic events. At all times mentioned in this Complaint, Defendants, and their predecessors and successors in interest, intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from Plaintiff and Plaintiff's health care providers with the intent to defraud.

147. Neither Plaintiff nor Plaintiff's health care providers were aware of the facts set forth above. Had Defendants not concealed such information, Testim would not have been used to treat Plaintiff.

148. Had Plaintiff or his health care providers been made aware of the increased risks of serious injury associated with Testim, Plaintiff would not have used Testim.

149. Defendants' concealment of material facts was malicious, wanton, oppressive, and fraudulent such that it evidenced a willful and conscious disregard of the rights and safety of others.

150. As a direct and proximate consequence of Defendants' intentional concealment of facts, upon which Plaintiff and Plaintiff's health care providers reasonably relied, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees and such other, and further relief as this Court deems just and proper.

## N. EIGHTH CAUSE OF ACTION

## FRAUD: NEGLIGENT MISREPRESENTATION

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

151. Prior to Plaintiff's first dose of Testim, and during the period in which Plaintiff used Testim, Defendants misrepresented the degree to which Testim provided a safe and effective treatment.

152. Defendants failed to disclose material facts regarding the safety and efficacy of Testim, including information regarding increased adverse events and harmful side-effects.

153. Defendants had a duty to provide Plaintiff, physicians, and other patients with true and accurate information and warnings of any known risks and side-effects associated with the Testim products they marketed, distributed, and sold.

154. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failure associated with Testim that their representations regarding these drugs were false, and that they had a duty to disclose the dangers of Testim.

155. Defendants made the representations and otherwise failed to disclose material facts concerning Testim with the intent to induce patients, including Plaintiff, to act in reliance thereon in using Testim during the course of their treatment.

156. Plaintiff justifiably relied on Defendants' representations and non-disclosures in choosing to use Testim.

157. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## O. NINTH CAUSE OF ACTION

## VIOLATION OF UNFAIR AND DECEPTIVE TRADE PRACTICES ACTS

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges:

158. The State of Tennessee has enacted statutes to protect consumers against unfair or deceptive business practices, unfair competition and false advertising. *See* Tenn. Code Ann. §§ 47-18-103 *et seq.*

159. The acts and practices engaged in by Defendants, and described herein, constitute unlawful, unfair, deceptive, and/or fraudulent business practices, and violate Tennessee laws to protect consumers, including but not limited to, sections 47-18-104 and 47-18-109, of the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-103 *et seq.*

160. Defendants' acts and practices, as described herein, violate the state consumer protection laws, as set forth above, and/or (2) the justification for Defendants' conduct is outweighed by the gravity of the consequences to Plaintiff and the General Public, and/or (3) Defendants' conduct is immoral, unethical, oppressive, unscrupulous or substantially injurious to Plaintiff and the General Public, and/or (4) the conduct of Defendants constitutes fraudulent, untrue or misleading actions in that such conduct has a tendency to deceive Plaintiff and the General Public.

161. Defendants' unlawful, unfair and fraudulent business acts and practices are described herein and include, but are not limited to, the following:

a. Failed to accompany Testim with proper warnings regarding all possible adverse side effects associated with its use;

b. Failed to warn Plaintiffs prior to actually encouraging the sale of Testim either directly or indirectly through third parties or related entities.

c. Failed to warn that the risks associated with Testim would exceed the risks of other comparable forms of treatment;

d. Negligently marketed Testim despite the fact that the risk of the drug was so high and the benefits of the drug were so speculative that no reasonable pharmaceutical company, exercising due care, would have done so;

f. Recklessly, falsely, and deceptively represented, or knowingly omitted, suppressed or concealed, material facts regarding the safety and efficacy of Testim to or from the FDA and/or the FDA's advisory committee such that, had the FDA or its advisory committee members known of such facts, Testim would never have been approved and no physician would have been able to prescribe the drug to Plaintiffs;

g. Recklessly, falsely, and deceptively represented, or knowingly omitted, suppressed or concealed, material facts regarding the safety and efficacy of Testim to or from the consumer public such that, had the consumer public known of such facts, they would never have taken Testim;

h. Recklessly, falsely, and deceptively represented, or knowingly omitted, suppressed or concealed, material facts regarding the safety and efficacy of Testim to or from doctors and the medical community such that, had the doctors and the medical community public known of such facts, they would never have prescribed Testim nor advocated its use;

i. Remained silent, despite their knowledge of the growing public acceptance of their information and misrepresentations regarding the safety and efficacy of

Testim, and did so because the prospect of profits outweighed health and safety issues, all to the significant detriment of Plaintiffs; and

j. Failed to comply with their post-manufacturing duty to warn which arose when they knew, or with reasonable care should have known, that their drug was being prescribed without warning of the true risks of side effects.

162. Defendants' practices were misleading, deceptive, unfair and false to the consuming public in violation of the above-cited statutes.

163. Defendants' actions described herein occurred during the course of trade and commerce.

164. Defendants have injured the public interest, and Defendants' actions pose a continued threat to the public.

165. Defendants willfully failed to state a material fact and willfully used a falsehood as to a material fact.

166. As a direct and legal result of the misleading, deceptive, unfair and false trade practices of Defendants, Plaintiff sustained damages. Plaintiff is therefore entitled to equitable relief, including restitution of all monies paid for Testim, disgorgement of all profits accruing to Defendants because of their unlawful, unfair and fraudulent practices, all other consequential damages, the cost of medical monitoring for future prescription testosterone-related disease, illness or complications, attorneys' fees and costs, and a permanent injunction enjoining Defendants from their unlawful, unfair and fraudulent activities.

## P. PUNITIVE DAMAGES ALLEGATIONS

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full and further alleges:

167. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Testim users and for the primary purpose of

increasing Defendants' profits from the sale and distribution of Testim. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

168. Prior to the manufacturing, sale, and distribution of Testim, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Testim.

169. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Testim and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Testim. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of that Testim knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

170. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory, exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

## Q. GLOBAL PRAYER FOR RELIEF

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth here in full and further prays:

171. So far as the law and this Court allows, Plaintiff demands judgment against each Defendant on each count as follows:

a. Compensatory damages for the described losses with respect to each cause of action;

b. Past and future medical expenses;

c. Past and future lost wages and loss of earning capacity;

d. Past and future emotional distress;

e. Consequential damages;

f. Disgorgement of profits obtained through unjust enrichment;

g. Restitution;

h. Punitive damages with respect to each cause of action;

i. Reasonable attorneys' fees where recoverable;

j. Costs of this action;

k. Pre-judgment and all other interest recoverable; and

l. Such other additional and further relief as Plaintiff may be entitled to in law or in equity.

## R. DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all issues so triable.

DATED: July 31, 2014

Respectfully submitted,

/s/ Marvin B. Berke

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